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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,034	11/19/2003	Uri Herzberg	60004 (72021)	7145

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
06/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,034	HERZBERG ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,25-57 and 59-71* is/are pending in the application.

4a) Of the above claim(s) *1-6,25-42,53-57 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-52, 60-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/23/2009 has been entered.

Currently, claims 1-6, 25-57, 59-71 are pending. Claims 1-6, 25-42, 53-57 and 59 have been withdrawn from consideration and claims 43-52 and 60-71 are under examination herein.

Response to Arguments

Applicants continue to argue that the Kyle patent (US Patent 6,974,818) is not an effective reference for the purposes of 35 USC 102(e). Applicants argue that the disclosure of the Kyle patent cannot be used in a rejection under 35 USC 102(e) unless such disclosure is present in an application to which Kyle claims priority. Applicants argue that the priority application that the Kyle patent claims priority to (60/411,084) does not disclose the critical added limitations from the Kyle patent.

In response to the above argument, and as previously discussed, it is noted that the priority document teaches that Thiadiazolepiperazine compounds treat an addictive disorder. Treatment of addictive disorders encompasses treating tolerance; therefore,

the priority document of Kyle does teach the treatment of addictive disorders and is considered a viable priority document for the Kyle patent.

Applicants have carried forth the same arguments for the 35 USC 103 rejection, which have been addressed above and the rejection is maintained.

Claim Rejections – 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 43-45 and 48-50 rejected under 35 U.S.C. 102(e) as being anticipated by Kyle et al. (US Patent 6,974,818) as evidenced by Goodman & Gilman's (2001, pages 586-587).

Kyle et al. teach compounds that inhibit vanilloid receptor 1 (VR1) function in a cell (Col. 12, lines 19-22). These compounds are administered to animals of need of treatment for addictive disorders, including opioid dependence (Col. 5, lines 19-30, Col. 31, lines 18-25 and Col. 32, line 32). Example 6 outlines a study proving that the compounds of the Kyle et al. invention are capable of decreasing morphine self-administration (thereby inhibiting tolerance), which is a model for an addictive disorder.

Goodman & Gilman's teaches that the development of tolerance with repeated use is a characteristic feature of all the opioid drugs. Therefore it is inherent that a patient will be continuously or repeatedly administering the opioid narcotic analgesic and it would inherently follow that a patient will administer a treatment to block the ability to develop tolerance with the opioid analgesic.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 46-47, 51-52 and 60-71 rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al. (US Patent 6,974,818) as applied to claims 43-45 and 48-50 in the above rejection, in view of Bakthavatchalam et al. (US Patent 6,723,730).

Kyle et al. teach compounds that inhibit the vanilloid receptor that decrease morphine self-administration thereby decreasing tolerance.

Kyle et al. does not teach the K_i value of the VR1 antagonist or the dose of the opioid narcotic analgesic.

Kyle et al. does teach that the VR1 antagonist of the invention can act synergistically with the therapeutic agent (Col. 47, lines 53-67). Therefore, it would be

obvious to vary and/or optimize the amount of the opioid narcotic analgesic provided in the composition, according to the guidance provided by Kyle et al., to provide a composition having the desired properties such as the desired concentrations of the opioid narcotic analgesic to provide analgesia while not developing tolerance. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Bakthavatchalam et al. teach VR1 antagonists that exhibit K_i values less than 1 micromolar and 100 nanomolar (Col. 17, lines 30-38). Further Bakthavatchalam et al. teach various VR1 receptor antagonists that are multi-aryl (see Table III).

Accordingly, it would be obvious to a person of skill in the art to combine the inventions of Kyle et al. which teach that compounds that inhibit the VR1 receptor are effective in inhibiting the development of tolerance to narcotic analgesics, namely morphine, with the invention of Bakthavatchalam et al. which teach various VR1 antagonists with the claimed K_i values and compounds that are multi-aryl. One would be motivated to combine the prior art references because it is taught by Kyle et al. that VR1 antagonists are useful in treating addictive disorders and because Bakthavatchalam et al. teach VR1 antagonists, one would reasonably expect the same result of inhibition of tolerance to narcotic analgesics.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617